Papers

Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence

Karen Ward, Paul Hilton on behalf of the United Kingdom and Ireland Tension-free Vaginal Tape Trial Group

Abstract

Objective To compare tension-free vaginal tape with colposuspension as primary treatment for stress incontinence.

Design Multicentred randomised comparative trial.

Setting Gynaecology or urology departments in 14 centres in the United Kingdom and Eire, including university teaching hospitals and district general hospitals.

Participants 344 women with urodynamic stress incontinence; 175 randomised to tension-free vaginal tape and 169 to colposuspension

Main outcome measures Assessment before treatment and at six months postoperatively with the SF-36, the Bristol female lower urinary tract symptoms questionnaire, the EQ-5D health questionnaire, a one week urinary diary, one hour perineal pad test, cystometry, and, in some centres, urethral profilometry.

Results 23 women in the colposuspension group and 5 in the vaginal tape group withdrew before surgery. No significant difference was found between the groups for cure rates: 115 (66%) women in the vaginal tape group and 97 (57%) in the colposuspension group were objectively cured (95% confidence interval for difference in cure −4.7% to 21.3%). Bladder injury was more common during the vaginal tape procedure; postoperative complications, in particular delayed resumption of micturition, were more common after colposuspension. Operation time, duration of hospital stay, and return to normal activity were all longer after colposuspension than after the vaginal tape procedure.

Conclusion Surgery with tension-free vaginal tape is associated with more operative complications than colposuspension, but colposuspension is associated with more postoperative complications and longer recovery. Vaginal tape shows promise for the treatment of urodynamic stress incontinence because of minimal access and rapid recovery times; cure rates at six months were comparable with colposuspension.

Introduction

Urinary incontinence is reported by 14% of women, and urodynamic stress incontinence—the involuntary leakage of urine during increased abdominal pressure in the absence of a detrusor contraction—is diagnosed in over half of the women presenting to hospital with urinary incontinence.[1–3] Cure rates of around 50% are reported with physiotherapy,[4] and surgery is recommended for those women who fail to respond. Systematic reviews have shown that colposuspension has the best surgical results when compared with other treatments for urodynamic stress incontinence, with cure rates of up to 90% in women who have had no previous surgery for incontinence, although there are only limited data from randomised trials on which to base clinical practice.[5 6] Previous studies have been criticised for insufficient numbers of participants and statistical power as well as lack of standardised criteria for entry to the study and outcome measures.[6] Although colposuspension remains the most popular choice for the treatment of stress incontinence, some authors have reported less than half of patients remaining dry and free of complications long term.[7–9] Complications include haemorrhage, haematoma, bladder injury, and urinary tract infection. Up to 20% of women may develop de novo detrusor overactivity[5 9]; voiding dysfunction has been reported in 3% to 32% of women, and surgery for vaginal prolapse may be required in 2.5% to 26.7% after the procedure.[5]

The tension-free vaginal tape procedure is a relatively recent treatment for stress incontinence.[10] A polypropylene tape is inserted suburethrally under local anaesthesia with sedation. The procedure is thought to work by providing a pubourethral "neoligament." Increased intra-abdominal pressure results in a kink at the point of fixation, which prevents urine flow. Data from three early case series suggest objective cure rates of 84-100%, with few complications.[10–12] We compared the tension-free vaginal tape procedure with colposuspension in a prospective randomised manner, on a multicentre basis, using defined valid outcomes, including objective and subjective measures.

Methods

Women with stress incontinence, who had completed their family, were invited to take part. Exclusion criteria were detrusor overactivity, vaginal prolapse requiring

Department of Obstetrics and Gynaecology, University of Newcastle upon Tyne NE1 4LP
Karen Ward
clinical research associate

Directorate of Women's Services, Royal Victoria Infirmary, Newcastle upon Tyne NE1 4LP
Paul Hilton
consultant

Correspondence to:
P Hilton
paul.hilton@ncl.ac.uk

bmj.com 2002;325:67

treatment, previous surgery for prolapse or incontinence, a major degree of voiding dysfunction (defined at cystometry as a voiding pressure >50 cm H_20, maximum flow <15 ml/s, and residual urine volume >100 ml), neurological disease, and allergy to local anaesthetic.

The trial was conducted at gynaecology or urology departments in 14 centres in the United Kingdom and Eire, including university teaching hospitals and district general hospitals. Women were recruited from outpatient clinics once surgery had been selected for their stress incontinence.

The sample size calculation was performed assuming a 90% cure rate with colposuspension, and that a 10% difference in cure rate between procedures would be clinically important.[5] To detect this level of difference with 80% power would require 197 patients in each arm of the trial; to detect the same difference with 90% power, 262 patients were required in each arm. Calculations based on anticipated throughput of the collaborating units gave a pragmatic recruitment target of 436 patients. Recruitment was limited to the period May 1998 to August 1999 owing to logistic and financial constraints.

Researchers randomised participants via a telephone system, which allocated trial identification number and treatment group. Randomisation was computer generated using blocks of four and six. Owing to differences between the procedures in incision, anaesthesia, and catheterisation, it was not possible to blind investigators or participants to the treatment allocation.

The tension-free vaginal tape procedure was performed as described by Ulmsten, under local anaesthesia and sedation.[10] The bladder was not routinely catheterised after surgery. When bladder perforation or injury occurred an indwelling catheter was placed for 48 hours. Colposuspension was performed according to the standard technique used by the units. Before the start of the trial all investigators underwent training in the vaginal tape procedure in a recognised centre. The number of patients required for training varied between surgeons, who began recruiting when they were satisfied with their own technique.

At initial assessment, urodynamic evaluation was performed by medium fill dual channel subtracted cystometry with simultaneous pressure and flow voiding studies or videocystourethrography; in some centres urethral pressure profilometry at rest and at stress was also carried out.[13] Patients were asked to complete a urinary diary for one week, and a one hour perineal pad test was performed according to the recommendations of the International Continence Society.[3]

Patients' perceptions of changes in their symptoms and treatment outcome were measured with the generic SF-36 and the disease specific Bristol female lower urinary tract symptoms questionnaire.[14 15] Six weeks after surgery a postal questionnaire was sent out comprising the SF-36 and questions about recovery. Six months after surgery reassessment was undertaken with symptom review, clinical examination, the one hour pad test, and urodynamic studies. The SF-36 and Bristol female lower urinary tract symptoms questionnaires were completed by the patient in the clinic, and they were given a urinary diary to complete over one week and return by post.

Outcome measures

The primary outcome measure was objective cure of stress incontinence based on a negative stress test on urodynamic testing, combined with a negative one hour pad test (<1 g change in weight). Secondary outcome measures included subjective cure of incontinence and the development of voiding problems, urge symptoms, and vaginal prolapse. These were measured with the Bristol female lower urinary tract symptoms questionnaire and by interview with patients.

Statistical analysis

Data were entered into a database (Access, Microsoft) from case report forms by using double data entry. Entries were compared and any discrepancies reviewed by a third person. The data were analysed after quality control checks and resolution of queries. Urodynamic traces were also subjected to quality control checks. Objective and subjective cure rates were tested with the Cochran-Mantel-Haenzel test. Unpaired data were analysed with the Wilcoxon rank sum test and paired data with the Wilcoxon matched pairs test. Treatment differences in the incidence of adverse events and complications were tested with Fisher's exact test. Analysis of results was by intention to treat. The methods, definitions, and units conform to the standards proposed by the International Continence Society, except where specifically noted.[3]

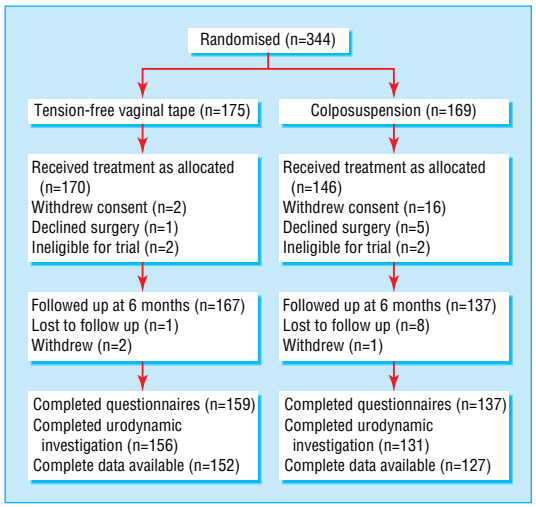
Ethics

Ethical approval for the trial was obtained from the multicentre research ethics committee as well as local ethics committees of the collaborating centres. The trial was carried out in accordance with "Recommendations guiding research into human subjects" (Declaration of Helsinki, 1975), "Good clinical practice for trials on medical products in the European Community" (WHO and ICH Tripartite Good Clinical Practice guidelines, 1997), and "Clinical investigation of medical devices for human subjects" (European standard of BS EN 540, 1993).

Results

Overall, 344 women were randomised over 15 months (figure). Table 1 shows the baseline characteristics of the two groups. Five patients who underwent surgery violated the protocol exclusion criteria; two in each arm had detrusor overactivity and one in the vaginal tape arm had voiding dysfunction. These patients are included in the analysis. The baseline characteristics of the patients who withdrew before surgery were similar to the participants, with the exception of a lower change in pad weight in the colposuspension group (median weight change for withdrawals 6 g (interquartile range 1-20) *v* 16 (6-38) for those undergoing surgery; P=0.0185, Wilcoxon rank sum test).

Operative complications were more common after the vaginal tape procedure (table 2), largely injury to the bladder and vagina. Operation times, blood loss, analgesic requirements, postoperative complications, and catheterisation were greater in the colposuspension group than the vaginal tape group.



Flow of participants through trial

Table 1 Baseline characteristics of 344 women allocated tension-free vaginal tape procedure or colposuspension for stress incontinence. Values are medians (interquartile ranges) unless stated otherwise

	Vaginal tape group (n=175)	Colposuspension group (n=169)
Age (years)	50 (42-56)	50 (45-59)
Parity	2 (2-3)	2 (2-3)
Body mass index	27 (24-30)	27 (24-30)
No (%) menopausal	71 (41)	68 (40)
No (%) with previous hysterectomy	53 (30)	54 (32)
No (%) using systemic hormone replacement therapy	59 (34)	60 (36)

Primary outcome measure

A negative one hour pad test was recorded in 128 (73%) patients in the vaginal tape group and 109 (64%) in the colposuspension group (table 3). The change in pad weight decreased significantly in both groups, but there was no significant difference between the groups. Stress testing for urodynamic stress incontinence was negative at cystometry in 142 (81%) patients after the vaginal tape procedure and 114 (67%) after colposuspension. Objective cure, defined as a negative pad test and negative cystometry, was found in 115 (66%) patients in the vaginal tape group and 97 (57%) in the colposuspension group (P=0.099, Cochran-Mantel-Haenzel test; 95% confidence interval for difference in cure −4.7% to 21.3%).

Secondary outcome measures

Both groups showed significant changes in most urinary symptoms at six months, although there was no significant difference between the vaginal tape procedure and colposuspension for any of these items (table 4). Only 63 (36%) patients in the vaginal tape arm and 48 (28%) in the colposuspension arm reported no leakage under any circumstance after surgery (Bristol female lower urinary tract symptoms questions 4 and 6-9): the number of women reporting cure of stress leakage was 103 (59%) and 90 (53%), respectively (question 7).

The responses for the SF-36 were combined and transformed to generate eight health dimensions, with a potential score of 0 to 100 (table 5).[16] Higher scores indicate better perceived health. Significant differences were seen at six weeks in emotional, social, and physical function and vitality, with the colposuspension group having lower scores than the vaginal tape group. By six months, scores in the colposuspension group had shown significantly less improvement in emotional and social functioning, vitality, and mental health than those in the tape group. Table 2 includes patients' perception of return to normality.

Discussion

In the short term, the tension-free vaginal tape procedure is as effective as colposuspension for the treatment of primary stress incontinence. Operative complications were more common after the vaginal tape

Table 2 Operative, admission, and postoperative details of women allocated tension-free vaginal tape procedure or colposuspension. Values are numbers (percentages) unless stated otherwise

	Vaginal tape group (n=170)	Colposuspension group (n=146)	P value
Median (interquartile range) theatre times (min):			
Holding bay	5 (5-10)	5 (5-12)	0.48*
Anaesthetic room	15 (10-50)	17 (14-25)	<0.001*
Operating theatre	40 (30-48)	50 (35-60)	<0.001*
Recovery area	41 (31-60)	85 (65-115)	<0.001*
Anaesthesia:			
General	3 (2)†	145 (99)	
Spinal	3 (2)‡	1 (1)	
Local and sedation	164 (96)	Not applicable	
Median (interquartile range) blood loss (ml)	50 (30-100)	128 (74-200)	<0.001*
Opiate analgesia used in first 24 hours postoperatively	35 (21)	133 (91)	<0.001§
Duration of catheterisation (suprapubic, urethral, or intermittent):			
1-7 days	64 (38)	146 (100)	
8-28 days	9 (5)	48 (33)	<0.0001§
29 days to 6 months	5 (3)	19 (13)	<0.001§
>6 months	5 (3)	11 (8)	0.0746§
Complications:			
Bladder injury (perforation or evidence of trauma)	15 (9)	3 (2)	0.013§
Vaginal perforation	5 (3)	0	0.06§
Wound infection	4 (2)	10 (7)	0.06§
Fever**	1 (1)	7 (5)	0.027§
Deep vein thrombosis	0	3 (2)	0.10§
Incisional hernia	Not applicable	3 (2)	
Retropubic haematoma	3 (2)	0	0.25§
Vascular injury¶	1 (1)	0	1.0§
Tape erosion	1 (1)	Not applicable	
Urinary tract infection (in six weeks after surgery)	38 (22)	46 (32)	0.074§
Total complications (excluding fever)**	67 (39)	65 (44.5)	0.36§
Median (interquartile range) postoperative hospital stay (days)	1 (1-2)	5 (5-7)	<0.001*
Median (interquartile range) time to return to normal activities (weeks)	3 (2-4)	6 (4-8)	<0.001*
Median (interquartile range) time to return to work (weeks)	4 (3-7)	10 (8-12)	<0.001*
Response to procedure:			
Satisfied or very satisfied	145 (85)	119 (82)	
Dissatisfied	7 (4)	4 (3)	
Would recommend to relative or friend	143 (84)	119 (82)	

*Wilcoxon rank sum test.
†General anaesthesia induced during procedure because of poor respiratory effort in one case, methaemoglobinaemia after injection of prilocaine in another, and for discomfort in third.
‡Breached protocol.
§Fisher's exact test.
¶Abnormal obturator artery injured requiring laparotomy and blood transfusion (4 units).
**Considerable overlap between postoperative fever and wound infection, hence fever excluded from totals.

Table 3 Urodynamic and urinary diary data before and after surgery in women allocated tension-free vaginal tape procedure or colposuspension. Values are medians (interquartile ranges) unless stated otherwise

	Vaginal tape group		Colposuspension group		
	Before surgery	6 months postoperatively	Before surgery	6 months postoperatively	P value*
Cystometry:	(n=175)	(n=159)	(n=169)	(n=134)	
Volume at first desire to void (ml)	194 (140-270)	236 (146-298)	189 (139-249)	217 (172-289)	0.71
Cystometric capacity (ml)	461 (407-503)	450 (400-500)	450 (396-500)	443 (400-502)	0.39
Maximum flow rate (ml/s)	25 (19-33)	20 (15-25)	24 (18-34)	20 (14-26)	0.38
Maximum voiding pressure (cm H_2O)	28 (15-38)	30 (20-38)	25 (18-38)	30 (20-40)	0.63
Post micturition residual (ml)	0	0 (0-50)	0 (0-7)	0 (0-35)	0.59
No (%) with voiding disorder†	1 (1)	11 (9)	0	8 (7)	0.76
No (%) with genuine stress incontinence‡	175 (100)	17 (11)	169 (100)	20 (15)	
No (%) with unstable detrusor contractions (with or without symptoms)‡	2 (1)	12 (8)	2 (1)	13 (10)	0.58
Urethral pressure profilometry:	(n=81)	(n=82)	(n=70)	(n=71)	
Functional urethral length at rest (mm)	29 (26-37)	30 (24-34)	29 (27-33)	34 (30-37)	0.07
Maximum urethral closure pressure at rest (mm)	45 (27-56)	37 (26-52)	51 (31-60)	46 (38-37)	0.085
Functional urethral length at cough (mm)	0 (0-21)	20 (17-26)	0 (0-13)	25 (20-29)	0.12
Maximum urethral closure pressure at cough (mm)	0 (0-15)	45 (32-60)	0 (0-19)	52 (34-87)	0.24
Pressure transmission ratio (%):					
1st quarter	86 (80-93)	100 (90-100)	91 (86-100)	110 (100-118)	0.48
2nd quarter	80 (75-86)	105 (100-118)	78 (75-82)	113 (100-140)	0.56
3rd quarter	57 (44-64)	93 (68-107)	60 (52-71)	85 (65-114)	0.77
4th quarter	19 (10-28)	29 (18-43)	30 (13-35)	38 (24-44)	0.67
1 hour perineal pad test:	(n=170)	(n=150)	(n=157)	(n=128)	
Change in pad weight (g)	18 (6-36)	0 (0-0.2)	16 (6-38)	0 (0-0.3)	0.83
No (%) with weight change <1g	4 (2)	128 (73)	5 (3)	109 (65)	
Frequency volume data:	(n=113)	(n=76)	(n=99)	(n=47)	
Voided volume per 24 hours (ml)	1739 (1400-2187)	1824 (1383-2133)	1714 (1407-2088)	1696 (1375-2048)	0.77
Average voided volume (ml)	221 (180-274)	262 (216-319)	237 (164-286)	232 (187-304)	0.15
Micturition over 24 hours	8 (6-10)	7 (5-8)	7 (6-10)	7 (6-8)	0.073
Episodes of nocturia	1 (0-1)	1 (0-1)	1 (0-1)	1 (0-1)	0.022
Leaks over 24 hours§	3 (1-5)	0	2 (1-4)	0	0.67

*Wilcoxon rank sum test, comparing change from baseline to review between two groups.
†Two out of three of peak flow <15 ml/s, maximum voiding pressure >50 cm H_2O, and residual volume >100ml, given as percentage of patients with complete postoperative voiding data (n=121 for vaginal tape, n=110 for colposuspension).
‡Percentage of patients undergoing repeat investigation (n=159 for vaginal tape, n=134 for colposuspension).
§Significant reduction in leakage episodes after surgery in both groups (P<0.0001, Wilcoxon matched pairs test).

procedure; colposuspension was associated with more postoperative complications and longer recovery.

Blinding may be possible in a trial of surgery for stress incontinence, as shown in a trial of laparoscopic versus open colposuspension.[17] We believed that patients in our trial would be aware of their allocated treatment owing to differences between the procedures in incision, anaesthesia, and catheterisation. Staff undertaking postoperative assessments were not blinded to the procedure for logistical reasons, and will have been vulnerable to observer bias.

Surgery and anaesthesia for the vaginal tape procedure was standardised and was performed as described by Ulmsten.[10] Although colposuspension was performed according to that used by the units it was standardised for numbers of suspensory sutures, suture material, and postoperative catheterisation. The investigators all had expertise in continence surgery, but were from a mixed background including gynaecologists, urogynaecologists, and urologists and represented both general hospitals and university teaching hospitals. All surgeons had undergone similar training in the vaginal tape procedure, although they had variable experience before recruitment. The group therefore reflects the current practice in the United Kingdom and Eire and as such increases the external validity of the study.

The number of patients recruited fell short of the target determined by a sample size calculation owing to limitations of resources and time. Although differences between the procedures for cure of stress incontinence were not shown, the numbers were not sufficient to achieve the power required to assume equivalence. Given that the objective cure for colposuspension was lower than expected from previous literature, the numbers recruited would give only 50% power to detect a 10% difference or 80% power to detect a 15% difference in cure rates.

No differences were shown between the vaginal tape procedure and colposuspension for objective cure of urodynamic stress incontinence, as measured by the pad test and urodynamic testing. Objective cure rates are lower than those previously reported. This may be due to the stricter definition of cure in this study. There has been little consistency in the objective outcome measures used in previous studies, and cure rates are often quoted for single tests. The cure rates for both procedures as measured by single urodynamic tests range from 74% to 84% and are comparable to those reported in previous series. Most reports of incontinence surgery give no information on non-attenders or the handling of missing data. They have by default assumed that non-attenders are equivalent to attenders. We have considered non-attenders or patients with missing data as treatment failures.

Urodynamic changes

Urodynamic assessment showed a reduction in maximum flow rate but no significant change in

Table 4 Responses to Bristol female urinary tract symptoms questionnaire before and six months after tension-free vaginal tape procedure or colposuspension. Unless stated otherwise, values are numbers (percentages) of all patients reporting individual symptoms and for those reporting symptoms as bit of a problem, quite a problem, or serious problem

	Vaginal tape group				Colposuspension group				P value*	
	Before surgery (n=168)		6 months postoperatively (n=159)		Before surgery (n=154)		6 months postoperatively (n=127)			
Symptom	Reporting symptom	Reporting symptom as problem	Reporting symptom	Reporting symptom as problem	Reporting symptom	Reporting symptom as problem	Reporting symptom	Reporting symptom as problem	Reporting symptom	Reporting symptom as problem
Urinary symptoms:										
Daytime frequency (>7)†	134 (80)	128 (76)	78 (49)	33 (21)	122 (79)	105 (68)	64 (50)	18 (14)	0.85	0.72
Night time frequency (>0)†	134 (80)	92 (55)	99 (62)	33 (21)	126 (82)	83 (54)	83 (65)	24 (19)	0.75	0.82
Urgency†	160 (95)	139 (83)	116 (73)	51 (32)	149 (97)	126 (82)	100 (79)	42 (33)	0.54	0.88
Urge incontinence†	160 (95)	160 (95)	84 (53)	49 (31)	148 (96)	143 (93)	69 (54)	43 (34)	0.82	0.65
Bladder pain	84 (50)	72 (43)	49 (31)	29 (18)	63 (41)	54 (35)	36 (28)	20 (16)	0.02	0.09
Stress incontinence†	168 (100)	168 (100)	54 (34)	35 (22)	154 (100)	152 (99)	37 (29)	22 (17)	0.95	0.70
Unexplained incontinence†	143 (85)	139 (83)	27 (17)	25 (16)	129 (84)	126 (82)	17 (13)	17 (13)	0.90	0.88
Nocturnal enuresis†	76 (45)	72 (43)	14 (9)	13 (8)	72 (47)	74 (48)	11 (9)	9 (7)	0.90	0.29
Frequency of incontinent episodes (>never)†	166 (99)	166 (99)	72 (45)	41 (26)	154 (100)	154 (100)	66 (52)	32 (25)	0.55	0.17
Quantity of urine loss (>none)†	165 (98)	NA	70 (44)	NA	154 (100)	NA	55 (43)	NA	0.27	NA
Wearing protection†	161 (96)	NA	45 (28)	NA	146 (95)	NA	30 (24)	NA	0.68	0.17
Changing outer clothing†	139 (83)	NA	35 (22)	NA	119 (77)	NA	37 (29)	NA	0.15	NA
Hesitancy	57 (34)	45 (27)	75 (47)	13 (21)	54 (36)	43 (28)	70 (55)	15 (12)	0.06	0.89
Straining	18 (11)	17 (10)	25 (16)	10 (6)	23 (15)	23 (15)	25 (20)	10 (8)	0.24	0.69
Intermittent stream	67 (40)	40 (24)	68 (43)	10 (6)	62 (40)	39 (25)	69 (54)	11 (9)	0.0015	0.68
Abnormal urinary stream	66 (39)	45 (27)	91 (57)	17 (11)	57 (37)	42 (27)	86 (68)	15 (12)	0.015	0.91
History of retention	5 (3)	NA	8 (5)	NA	5 (3)	NA	6 (5)	NA	0.91	NA
Dysuria	60 (36)	47 (28)	38 (24)	24 (15)	52 (34)	39 (25)	29 (23)	20 (16)	0.13	0.16
Incomplete emptying†	131 (78)	104 (62)	86 (54)	37 (23)	114 (74)	95 (62)	66 (52)	28 (22)	0.84	0.93
Inability to stop midstream†	131 (78)	NA	59 (37)	NA	120 (78)	NA	57 (45)	NA	0.11	NA
Sexual questions:										
Pain due to dry vagina	57 (34)	57 (34)	51 (32)	32 (20)	60 (39)	54 (36)	38 (30)	32 (25)	0.97	0.40
Sex life spoilt by symptoms†	121 (72)	118 (70)	49 (31)	43 (27)	97 (63)	95 (62)	34 (27)	33 (26)	0.22	0.54
Pain with intercourse	59 (35)	62 (37)	38 (24)	33 (21)	49 (32)	46 (30)	22 (17)	25 (20)	0.59	0.097
Incontinence with intercourse†	101 (60)	99 (59)	22 (14)	22 (14)	97 (63)	91 (59)	14 (11)	9 (7)	0.85	0.41
Lifestyle questions:										
Fluid restriction†	121 (72)	99 (59)	62 (39)	25 (16)	109 (71)	83 (54)	47 (37)	14 (11)	0.78	0.72
Ability to perform daily tasks†	136 (81)	129 (77)	25 (16)	21 (13)	126 (82)	126 (82)	19 (15)	10 (8)	0.77	0.44
Avoiding places or situations†	123 (73)	121 (72)	52 (33)	30 (19)	114 (74)	114 (74)	41 (32)	28 (22)	0.82	0.96
Interfering with physical activity†	160 (95)	160 (95)	32 (20)	32 (20)	143 (93)	140 (91)	22 (17)	18 (14)	0.92	0.82
Interfering with social relationships†	121 (72)	124 (74)	19 (12)	21 (13)	119 (77)	122 (79)	17 (13)	17 (13)	0.18	0.093
Interfering with life overall†	165 (98)	NA	48 (30)	NA	145 (94)	NA	28 (22)	NA	0.87	NA

NA=not applicable.
*Wilcoxon rank sum test, comparing change from baseline to review between two groups.
†Significant reduction in reporting of symptoms in both groups postoperatively (P<0.0001, Wilcoxon matched pairs test).

voiding pressure, for both the vaginal tape procedure and colposuspension. Reduced maximum flow and increased voiding pressures have been reported for both colposuspension and the vaginal tape procedure.[18–20] The rates of detrusor overactivity after the vaginal tape procedure and colposuspension are consistent with published data.[5 20]

No differences were seen in the urethral pressure profile between the procedures. Increases in stress variables and pressure transmission ratios have been

Table 5 Mean baseline SF-36 scores and change in score at 6 weeks and 6 months after vaginal tape procedure or colposuspension

	Baseline		Change (6 weeks)			Change (6 months)		
Dimension	Vaginal tape group (n=166)	Colposuspension group (n=141)	Vaginal tape group (n=144)	Colposuspension group (n=123)	P value for difference in change*	Vaginal tape group (n=159)	Colposuspension group (n=127)	P value for difference in change*
Physical function	65.5	66.2	11.0	4.8	0.002	17.5	16.7	0.75
Role physical	68.0	64.3	–18.0	–26.9	0.085	9.9	10.2	0.90
Role emotional	70.1	73.1	–0.9	–19.7	<0.001	12.1	5.4	0.05
Social functioning	74.5	77.0	–0.4	–11.9	<0.001	11.7	4.0	0.028
Mental health	66.0	67.4	3.7	1.5	0.36	7.9	2.7	0.023
Energy/vitality	51.6	53.0	–1.7	–7.1	0.013	8.7	3.6	0.035
Pain	75.4	76.6	–8.8	–14.0	0.11	1.1	–1.5	0.49
General health	69.9	69.3	0.8	0.6	0.80	1.5	2.4	0.98

Significant values indicate difference in treatments.
*Wilcoxon rank sum test.

described after colposuspension and have been attributed to repositioning of the bladder neck in proximity to the pubic symphysis.[19] The vaginal tape is placed at the mid-urethral level and causes minimal elevation; despite this the pattern of pressure transmission is not significantly different from that after colposuspension.

Symptom changes

Subjective cure rates were lower than reported elsewhere. Most studies have reported on an ill defined population, using non-validated methods. In a cohort study of surgery for stress incontinence surgeons were satisfied with the outcome of surgery in 85% of cases whereas only 28% of women said they were totally continent after surgery,[7] which is in keeping with our results.

The reduction in symptoms of urgency and urge incontinence in our study has been reported for both colposuspension and tension-free vaginal tape.[19 20] Patients perceived themselves to have returned to normal activity more rapidly after the vaginal tape procedure than after colposuspension. This is mirrored in the responses to the SF-36 at six weeks. However because patients were not blinded to their procedure, bias could have been introduced in the preoperative counselling, leading those undergoing colposuspension to expect a longer recovery.

Complications

The incidence of bladder injury after the vaginal tape procedure was high compared with published series and compared with other procedures for stress incontinence.[10 12 20] Bladder injury during the vaginal tape procedure seems to be a relatively minor complication resulting from needle perforation. The bladder is drained by catheter for up to 48 hours, but no long term sequelae have yet been reported. Bladder injury during colposuspension requires formal surgical closure and drainage for five days.

Vascular injury has been a concern with vaginal tape. We recorded one acute injury requiring laparotomy and three retropubic haematomas. The overall incidence of vascular injury is 32 per 250 000 (Gynecare, personal communication, 2002). The incidence of vascular injury after colposuspension has not been reported.

Erosion of inorganic material into the vagina, bladder, and urethra has been reported after several sling procedures and has resulted in the withdrawal of one device.[21] In our study there was one case of tape erosion. This was managed by partial excision of the tape and closure of the vaginal skin. In the five years since tension-free vaginal tape was first described there have been five reports of tape erosion into the urethra (Gynecare, personal communication, 2002). It is likely that this figure represents an underestimate, and long term follow up of these patients is needed to quantify the extent of this complication.

Long term voiding disorder is reported in up to 20% of patients after colposuspension.[18] Little data exist on voiding difficulty after the vaginal tape procedure although it seems infrequent.[20 22] More patients in our study required catheter drainage after colposuspension even though the overall rate of voiding disorder was low compared with published literature. Previous series may have included women with pre-existing voiding dysfunction, who were excluded from our study.

Long term follow up is needed to assess the continuing success of the two procedures and to provide further data on the development of prolapse and tape erosion; follow up to five years is planned.

What is already known on this topic

Few randomised trials exist on surgery for stress incontinence

Systematic reviews suggest that colposuspension is associated with cure rates of up to 90%

Case series of tension-free vaginal tape suggest cure rates of about 85%, with rapid return to normal activity

What this study adds

At six months the tension-free vaginal tape procedure is as effective as colposuspension for the primary treatment of stress incontinence

Operative complications were more common with vaginal tape, but duration of hospital stay and return to normal activity were shorter than with colposuspension

Postoperative complications were more common after colposuspension

We thank the patients and technical, secretarial, nursing, and medical staff of the participating hospitals, the monitoring staff of Ethicon, James Browning as the sponsor medical adviser to June 2000, Marjory Willins (trial manager), Jane Gibson (trial administration), Ailie Smith (quality assurance), and Peter Wilkinson (statistical advice and analysis).

Contributors: PH (principal investigator) and KW (trial coordinator) developed the idea for the study, designed the trial, participated in analysis of the data, and wrote the paper. The following were members of the United Kingdom and Ireland TVT trial group: Paul Abrams (Southmead Hospital, Bristol), Jonathan Bibby (Northampton General Hospital), Linda Cardozo (King's College Hospital), Malcolm Frazer and Ezzat Kozman (Warrington Hospital), Paul Hardiman (North Middlesex Hospital), Paul Hilton and Karen Ward (Royal Victoria Infirmary, Newcastle upon Tyne), David Holmes (St Paul's Hospital, Cheltenham), Mohsen Iskander (Southport General Hospital), Declan Keane (National Maternity Hospital, Dublin), Ash Monga (Princess Anne Hospital, Southampton), David Richmond (Liverpool Women's Hospital), David Sanderson (Colchester General Hospital), Stuart Stanton (St George's Hospital Medical School), and Andrew Thorpe (Sunderland Royal Infirmary).

Funding: None.

Competing interests: KW was supported by a grant from Ethicon, which also provided materials and additional support to collaborating centres. PH and KW have been reimbursed by Ethicon for expenses associated with attending conferences where this, and related work, has been presented.

1 Brocklehurst JC. Urinary incontinence in the community—analysis of a MORI poll. *BMJ* 1993;306:832-4.
2 Keane DP, Eckford SD, Shepherd AM, Abrams P. Referral patterns and diagnoses in women attending a urodynamic unit. *BMJ* 1992;305:808.
3 Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al. The standardisation of terminology of lower urinary tract function. *Neurourol Urodynamics* 2002;21:167-78.
4 Bo K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999;318:487-93.
5 Jarvis GJ. Surgery for genuine stress incontinence. *Brit J Obstet Gynaecol* 1994;101:371-4.

6 Black NA, Downs SH. The effectiveness of surgery for stress incontinence in women: a systematic review. *Brit J Urol* 1996;78:497-510.
7 Black N, Griffiths J, Pope C, Bowling A, Abel P. Impact of surgery for stress incontinence on morbidity: cohort study. *BMJ* 1997;315:1493-502.
8 Galloway N, Davies N, Stephenson T. The complications of colposuspension. *Brit J Urol* 1987;60:122-4.
9 Eriksen B, Hagen B, Eik-Nes S, Molne K, Mjolnerod D, Romslo I. Long-term effectiveness of the Burch colposuspension in female urinary stress incontinence. *Acta Obstet Gynecol Scand* 1990;69:45-50.
10 Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunc* 1996;7:81-6.
11 Nilsson CG. The tension free vaginal tape procedure (TVT) for treatment of female urinary incontinence. A minimal invasive surgical procedure. *Acta Obstet Gynecol Scand Suppl* 1998;168:34-7.
12 Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, et al. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynec J Pelvic Floor Dysfunc* 1998;9:210-3.
13 Hilton P, Stanton SL. Urethral pressure measurement by microtransducer: the results in symptom-free women and in those with genuine stress incontinence. *Brit J Obstet Gynaecol* 1983;90:919-33.
14 Jenkinson C, Coulter A, Wright L. Short form 36 (SF36) health survey questionnaire: normative data for adults of working age. *BMJ* 1993;306:1437-40.
15 Jackson S, Donovan J, Brookes S, Eckford S, Swithinbank L, Abrams P. The Bristol female lower urinary tract symptoms questionnaire: development and psychometric testing. *Brit J Urol* 1996;77:805-12.
16 Jenkinson C, Layte R, Wright L, Coulter A. *The UK SF-36: an analysis and interpretation manual*. Oxford: Health Services Research Unit, University of Oxford, 1996.
17 Carey M, Rosamilia A, Maher C, Cornish A, Murray C, Ugoni A. Laparoscopic versus open colposuspension: a prospective multicentre randomised single-blind comparison. *Neurourol Urodynamics* 2000;19:389-90.
18 Lose G, Jorgensen L, Mortensen SO, Molsted-Pedersen L, Kristensen JK. Voiding difficulties after colposuspension. *Obstet Gynecol* 1987;69:33-8.
19 Hilton P, Stanton SL. A clinical and urodynamic assessment of the Burch colposuspension for genuine stress incontinence. *Brit J Ostet Gynaecol* 1983;90:934-9.
20 Moran PA, Ward KL, Johnson D, Smirni WE, Hilton P, Bibby J. Tension-free vaginal tape for primary genuine stress incontinence: a two-centre follow-up study. *Brit J Urol Int* 2000;861:39-42.
21 Kobashi KC, Dmochowski R, Mee SL, Mostwin J, Nitti VW, Zimmern PE, et al. Erosion of woven polyester pubovaginal sling. *J Urol* 1999;162:2070-2.
22 Haab F, Sananes S, Amarenco G, Ciofu C, Uzan S, Gattegno B, et al. Results of the tension-free vaginal tape procedure for the treatment of type II stress urinary incontinence at a minimum followup of 1 year. *J Urol* 2001;165:159-62.

(Accepted 15 May 2002)